Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of patients with poor ovarian response included in the antagonist cycle during standard, dual and triple triggering in IVF outcomes

Protocol summary

Study aim
To compare IVF results in patients with poor ovarian response included in the antagonist cycle recieving standard, double, and triple ovarian stimulation

Design
Three-arm parallel-group randomized clinical trial with 108 patients allocated into three groups, enrolled between April 2023- October 2023.

Settings and conduct
POR patients referred to the infertility department of Al-Zahra Educational Hospital, Tabriz, are assessed for eligibility to participate in the study. The eligible patients undergo controlled ovarian stimulation using antagonist protocol. After the diameter of the follicles reaches 16-18 mm, the randomization of patients into the study groups will be conducted by a nurse, using sealed envelopes, each containing a study group. Staff and patients will not be blinded. After 34- 36 hours, oocytes will be retrieved and evaluated by an embryologist. Following fertilization of the eggs and assessing embryo quality, embryo transfer will be performed and patients will undergo a pregnancy test (after two weeks) and vaginal ultrasound (after six weeks).

Participants/Inclusion and exclusion criteria
Inclusion criteria: informed consent to participate in the experiment, the eligibility of patients for IVF, the presence of POR, age between 24-42 years old, BMI of 19-27, and male partner having normal sperm evaluations (WHO criteria). Exclusion criteria: The presence of uterine anomalies, severe male factor infertility, severe endometriosis, drug allergy, and medical conditions such as hypothyroidism and diabetes.

Intervention groups
POR patients are randomly divided into three groups: Group A, receiving human chorionic gonadotropin (hCG) (standard triggering), Group B, receiving hCG and decapeptide (as GnRHa) (dual triggering), and Group C, receiving hCG, Decapeptyl, and menotropin (hMG) (triple triggering).

Main outcome variables
Primary outcome: The number of high-quality embryos

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230702058644N1**
Registration date: **2023-08-12, 1402/05/21**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-12, 1402/05/21**
Update count: **0**

Registration date
2023-08-12, 1402/05/21

Registrant information

Name
Aliyeh Ghasemzadeh
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-11, 1402/04/20

Expected recruitment end date
2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of patients with poor ovarian response included in the antagonist cycle during standard, dual and triple triggering in IVF outcomes

Public title

Comparison of patients with poor ovarian response included in the antagonist cycle during standard, dual and triple triggering in IVF outcomes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

informed consent to participate in the study Age between 24-42 years old Body mass index of 19-27 The presence of POR (AFCI <7, AMH <1.5) Eligibility of the patient for IVF The absence of uterine abnormalities

Exclusion criteria:

Hypothalamic dysfunctions in the patient diabetes mellitus liver diseases heart diseases renal diseases epilepsy metabolic disorders

Age

From **24 years** old to **42 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be allocated to each study group by the balanced block randomization technique. The number of blocks and the size of each block are 36 and 3, respectively (A, B, and C). The order of study groups in each block will determine the order of allocations.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Comparison of patients with poor ovarian response included in the antagonist cycle during standard, dual and triple triggering in IVF outcomes

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Women's Reproductive Health Research Center, A lzahra Educational Hospital, Baghshomal square, South Artesh street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Approval date

2023-07-11, 1402/04/20

Ethics committee reference number

IR.TBZMED.REC.1402.287

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

infertilefertility

Primary outcomes

1

Description

The number of good quality embryos

Timepoint

3 days after fertilization

Method of measurement

High-quality cleavage stage embryos will have six cells or greater on day 3 and less than 10% fragmentation and symmetric blastomeres, according to the Istanbul consensus workshop.

Secondary outcomes

1

Description

number of retrieved oocytes

Timepoint

36 hours after triggering

Method of measurement

All oocyte retrievals will be performed under transvaginal ultrasound guidance and will be counted using light microscopy.

2

Description
the number of mature oocytes
Timepoint
36 hours after triggering
Method of measurement
All oocyte retrievals will be performed under transvaginal ultrasound guidance and the number of mature oocytes will be counted using light microscopy.

3

Description
the number of clinical pregnancies
Timepoint
the presence of gestation sac two weeks after a positive hCG blood test
Method of measurement
ultrasound scan

4

Description
implantation rate
Timepoint
at 6–7 weeks of pregnancy
Method of measurement
Implantation rate is calculated from the number of gestational sacs with a visible fetal heart on ultrasound scan divided by the total number of transferred embryos.

Intervention groups

1

Description
Control group: Standard triggering via the injection of human gonadotropic hormone (hCG)
Category
Treatment - Drugs

2

Description
Intervention group 1: dual triggering via hCG and Decapeptyl
Category
Treatment - Drugs

3

Description
Intervention group 2: triple triggering via administration of hCG, Decapeptyl, and menotropin
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Educational Hospital
Full name of responsible person
Dr. Aliyeh Ghasemzadeh
Street address
Alzahra Hospital, Artesh Street, Tabriz, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Aliyeh Ghasemzadeh
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
all collected deidentified IPD
When the data will become available and for how long
Our data can be potentially available on October 2023.
To whom data/document is available
People working in academic institutions
Under which criteria data/document could be used
None
From where data/document is obtainable
email address: zohrehmohammadi98@gmail.com
What processes are involved for a request to access data/document
Sending an email to the mentioned address and sending an identity proof that reveals the hiring academic institute is sufficient for us to share the data.
Comments